

1 SENATE BILL NO. 456
2 INTRODUCED BY T. VERMEIRE

3
4 A BILL FOR AN ACT ENTITLED: "AN ACT GENERALLY REVISING LAWS RELATED TO HEARING AID
5 DISPENSERS; REORGANIZING AND CLARIFYING GENERALLY APPLICABLE ADMINISTRATIVE
6 PROVISIONS; REMOVING REDUNDANT PROVISIONS; TRANSFERRING OVERSIGHT AUTHORITY FROM
7 THE BOARD OF HEARING AID DISPENSERS TO A DEPARTMENT OF LABOR AND INDUSTRY
8 PROGRAM; ELIMINATING REQUIRED LICENSURE OF A PERSON TO SELL OVER-THE-COUNTER
9 HEARING AIDS, MEDICAL EVALUATION REQUIREMENTS, AND RIGHT TO CANCEL CONTRACT;
10 EXTENDING RULEMAKING; AMENDING SECTIONS 37-1-401, 37-15-102, 37-15-103, 37-16-102, 37-16-103,
11 37-16-202, 37-16-301, 37-16-303, 37-16-402, 37-16-408, AND 37-16-411, MCA; AND REPEALING SECTIONS
12 2-15-1740, 37-16-201, 37-16-203, 37-16-304, 37-16-405, 37-16-406, AND 37-16-413, MCA."

13
14 WHEREAS, the United States Food and Drug Administration amended regulations effective October
15 17, 2022 (87 F.R. 50698, August 17, 2022), that preempt the Montana Code Annotated regulating the sale of
16 over-the-counter hearing aids.

17
18 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

19
20 **Section 1.** Section 37-1-401, MCA, is amended to read:

21 **"37-1-401. Uniform regulation for licensing programs without boards -- definitions.** As used in
22 this part, the following definitions apply:

- 23 (1) "Complaint" means a written allegation filed with the department that, if true, warrants an
24 injunction, disciplinary action against a licensee, or denial of an application submitted by a license applicant.
- 25 (2) "Department" means the department of labor and industry provided for in 2-15-1701.
- 26 (3) "Investigation" means the inquiry, analysis, audit, or other pursuit of information by the
27 department, with respect to a complaint or other information before the department, that is carried out for the
28 purpose of determining:

- 1 (a) whether a person has violated a provision of law justifying discipline against the person;
- 2 (b) the status of compliance with a stipulation or order of the department;
- 3 (c) whether a license should be granted, denied, or conditionally issued; or
- 4 (d) whether the department should seek an injunction.

5 (4) "License" means permission in the form of a license, permit, endorsement, certificate,
 6 recognition, or registration granted by the state of Montana to engage in a business activity or practice at a
 7 specific level in a profession or occupation governed by:

- 8 (a) Title 37, chapter 16, 35, 72, or 73; or
- 9 (b) Title 50, chapter 39, 74, or 76.

10 (5) "Profession" or "occupation" means a profession or occupation regulated by the department
 11 under the provisions of:

- 12 (a) Title 37, chapter 16, 35, 49, 72, or 73; or
- 13 (b) Title 50, chapter 39, 74, or 76."

14

15 **Section 2.** Section 37-15-102, MCA, is amended to read:

16 **"37-15-102. Definitions.** As used in this chapter, the following definitions apply:

17 (1) "Audiologist" means a person who practices audiology and who meets the qualifications set
 18 forth in this chapter. A person represents to the public that the person is an audiologist by incorporating in any
 19 title or description of services or functions that the person directly or indirectly performs the words "audiologist",
 20 "audiology", "audiometrist", "audiometry", "audiological", "audiometrics", "hearing clinician", "hearing clinic",
 21 "hearing therapist", "hearing therapy", "hearing center", "hearing aid audiologist", or any similar title or
 22 description of services.

23 (2) "Audiology assistant" means any person meeting the minimum requirements established by the
 24 board of speech-language pathologists and audiologists who works directly under the supervision of a licensed
 25 audiologist.

26 (3) "Board" means the board of speech-language pathologists and audiologists provided for in 2-
 27 15-1739.

28 (4) "Department" means the department of labor and industry provided for in Title 2, chapter 15,

1 part 17.

2 (5) "Facilitator" means a trained individual who is physically present with the patient and facilitates
3 telehealth at the direction of an audiologist or speech-language pathologist. A facilitator may be but is not
4 limited to an audiology assistant or a speech-language pathology assistant.

5 ~~(6)~~ "Over-the-counter hearing aid" has the definition specified in 21 CFR 800.30 in effect on
6 January 1, 2023.

7 ~~(6)(7)~~ "Patient" means a consumer of services from an audiologist, a speech-language pathologist, a
8 speech-language pathology assistant, or an audiology assistant, including a consumer of those services
9 provided through telehealth.

10 ~~(7)(8)~~ "Practice of audiology" means nonmedical diagnosis, assessment, and treatment services
11 relating to auditory and vestibular disorders as provided by board rule and includes the selling, dispensing, and
12 fitting of hearing aids.

13 ~~(8)(9)~~ "Practice of speech-language pathology" means nonmedical diagnosis, assessment, and
14 treatment services relating to speech-language pathology as provided by board rule.

15 ~~(10)~~ "Prescription hearing aid" has the definition specified in 21 CFR 801.422 in effect on January 1,
16 2023. The term does not include an over-the-counter hearing aid.

17 ~~(9)(11)~~ "Speech-language pathologist" means a person who practices speech-language pathology and
18 who meets the qualifications set forth in this chapter. A person represents to the public that the person is a
19 speech-language pathologist by incorporating in any title or description of services or functions that the person
20 directly or indirectly performs the words "speech pathologist", "speech pathology", "speech correctionist",
21 "speech corrections", "speech therapist", "speech therapy", "speech clinician", "speech clinic", "language
22 pathologist", "language pathology", "voice therapist", "voice therapy", "voice pathologist", "voice pathology",
23 "logopedist", "logopedics", "communicologist", "communicology", "aphasiologist", "aphasiology", "phoniatriest",
24 "language therapist", "language clinician", or any similar title or description of services or functions.

25 ~~(10)(12)~~ "Speech-language pathology assistant" means a person meeting the minimum requirements
26 established by the board who works directly under the supervision of a licensed speech-language pathologist.

27 ~~(11)(13)~~ "Telehealth" has the meaning provided in 37-2-305."
28

1 **Section 3.** Section 37-15-103, MCA, is amended to read:

2 **"37-15-103. Exemptions -- rulemaking.** (1) This chapter does not prevent a person licensed in this
3 state under any other law from engaging in the profession or business for which that person is licensed.

4 (2) This chapter does not restrict or prevent activities of a speech-language pathology or audiology
5 nature or the use of the official title of the position for which the activities were performed on the part of a
6 speech-language pathologist or audiologist employed by federal agencies.

7 (3) Those persons performing activities described in subsection (2) who are not licensed under this
8 chapter may perform those activities only within the confines of or under the jurisdiction of the organization in
9 which they are employed and may not offer speech-language pathology or audiology services to the public for
10 compensation over and above the salary they receive for performance of their official duties with organizations
11 by which they are employed. However, without obtaining a license under this chapter, these persons may
12 consult or disseminate their research findings and scientific information to other accredited academic
13 institutions or governmental agencies. They also may offer lectures to the public for a fee without being licensed
14 under this chapter.

15 (4) This chapter does not restrict the activities and services of a student in speech-language
16 pathology or audiology from pursuing a course of study in speech-language pathology or audiology at an
17 accredited or approved college or university or an approved clinical training facility. However, these activities
18 and services must constitute a part of a supervised course of study, and a fee may not accrue directly or
19 indirectly to the student. These students must be designated by the title "speech-language pathology or
20 audiology intern", "speech-language pathology or audiology trainee", or a title clearly indicating the training
21 status appropriate to the level of training.

22 (5) This chapter does not restrict a person from another state from offering speech-language
23 pathology or audiology services in this state if the services are performed for not more than 5 days in any
24 calendar year and if the services are performed in cooperation with a speech-language pathologist or
25 audiologist licensed under this chapter. However, by securing a temporary license from the board subject to
26 limitations that the board may impose, a person not a resident of this state who is not licensed under this
27 chapter but who is licensed under the law of another state that has established licensure requirements at least
28 equivalent to those established by this chapter may offer speech-language pathology or audiology services in

1 this state for not more than 30 days in any calendar year if the services are performed in cooperation with a
2 speech-language pathologist or audiologist licensed under this chapter.

3 (6) This chapter does not restrict a person holding a class A certificate issued by the conference of
4 executives of American schools of the deaf from performing the functions for which the person qualifies.

5 (7) This chapter does not restrict a person who is licensed in this state as a hearing aid dispenser
6 from performing the functions for which the person qualifies and that are described in Title 37, chapter 16.

7 (8) (a) An audiologist who sells, dispenses, or fits prescription hearing aids is exempt from the
8 licensing requirements or other provisions of Title 37, chapter 16, ~~except for the provisions of 37-16-304.~~

9 (b) The board may adopt rules pertaining to the selling, dispensing, and fitting of prescription
10 hearing aids and prescription hearing aid parts, attachments, and accessories."
11

12 **Section 4.** Section 37-16-102, MCA, is amended to read:

13 **"37-16-102. Definitions.** Unless the context requires otherwise, in this chapter, the following
14 definitions apply:

15 (1) ~~"Board" means the board of hearing aid dispensers provided for in 2-15-1740.~~

16 (2)(1) "Department" means the department of labor and industry provided for in Title 2, chapter 15,
17 part 17.

18 (3) ~~"Hearing aid" means an instrument or device designed for or represented as aiding or improving
19 defective human hearing and parts, attachments, or accessories of the instrument or device.~~

20 (4) ~~"License" means a regular or trainee license.~~

21 (2) "Licensed hearing aid dispenser" is an individual who fits, sells, and dispenses prescription
22 hearing aids.

23 (3) "Over-the-counter hearing aid" has the definition specified in 21 CFR 800.30 in effect on
24 January 1, 2023.

25 (5)(4) "Permanent place of business" means the primary site in this state at which a person licensed
26 under this chapter conducts testing and fitting of prescription hearing aids and related devices ~~and that is open~~
27 ~~to the public at least 5 days a week.~~

28 (6) ~~"Place of practice" means either a permanent place of business or a location on record with the~~

1 department at which a person licensed under this chapter makes occasional visits. A place of practice must be
2 affiliated with a permanent place of business.

3 ~~(7)~~(5) "Practice of selling, dispensing, and fitting prescription hearing aids" means the evaluation or
4 measurement of the powers or range of human hearing by means of an audiometer and a visual examination of
5 the ear and canal or by any other means devised and the consequent selection, adaption, sale, dispensing, or
6 fitting of prescription hearing aids intended to compensate for hearing loss, including eyeglass prescription
7 hearing aids and their fittings, and the making of an impression of the ear and the subsequent selection of a
8 proper ear mold, but does not include batteries, cords, or accessories.

9 (6) "Prescription hearing aid" has the definition specified in 21 CFR 801.422 in effect on January 1,
10 2023. The term does not include an over-the-counter hearing aid."

11

12 **Section 5.** Section 37-16-103, MCA, is amended to read:

13 "**37-16-103. Exemptions.** This chapter does not apply to a person who is:

- 14 (1) a physician licensed to practice by the state board of medical examiners;
- 15 (2) engaged in the practice of fitting prescription hearing aids if the person's practice is part of the
16 academic curriculum of an accredited institution of higher education or part of a program conducted by a public
17 agency; or
- 18 (3) licensed as an audiologist under the provisions of Title 37, chapter 15, ~~except that the~~
19 ~~provisions of 37-16-304 apply to licensed audiologists.~~"

20

21 **Section 6.** Section 37-16-202, MCA, is amended to read:

22 "**37-16-202. Powers and duties -- licensed hearing aid dispenser program.** ~~(1) The powers and~~
23 ~~duties of the board are to~~ The department may:

- 24 ~~(a) license persons who apply and are qualified to practice the fitting of hearing aids;~~
- 25 ~~(b) establish a procedure to initiate or receive, investigate, and process complaints from any source~~
26 ~~concerning the activities of persons licensed under this chapter;~~
- 27 ~~(c)~~(1) adopt rules necessary to carry out this chapter;
- 28 ~~(d)~~(2) require the periodic inspection and calibration of audiometric testing equipment; and

1 ~~(e) initiate legal action to enjoin from operation a person engaged in the sale, dispensing, or fitting of~~
2 ~~hearing aids in this state that is not licensed under this chapter;~~

3 ~~(f) adopt rules consistent with the provisions of 37-16-301, 37-16-303, 37-16-304, 37-16-402, 37-16-~~
4 ~~405, 37-16-408, and 37-16-411; and~~

5 ~~(g)(3) establish and adopt minimum requirements for the form of bills of sale and receipts.~~

6 ~~(2) Rules adopted by the board pursuant to subsection (1)(f) may include but are not limited to rules~~
7 ~~defining the term "related devices" and other rules necessary to implement 37-16-301, 37-16-303, 37-16-304,~~
8 ~~37-16-402, 37-16-405, 37-16-408, and 37-16-411."~~

9

10 **Section 7.** Section 37-16-301, MCA, is amended to read:

11 **"37-16-301. Permanent place of business in state necessary -- records -- notice -- designation**

12 **of licensee in charge.** ~~(1) A person who is actively engaged in dispensing hearing aids and related devices as~~

13 ~~a business licensed hearing aid dispenser must have a permanent place of business in this state that will be~~

14 ~~opened to serve the public, having the necessary testing, fitting, and hearing aid accessories needed by the~~

15 ~~hard-of-hearing public in the wearing of hearing aids and related devices. All licensed hearing aid dispensers~~

16 ~~shall identify their permanent place of business in all advertising public notices and in all consumer~~

17 ~~correspondence, both written and verbal. More than one hearing aid dispenser licensee may work from a~~

18 ~~permanent place of business.~~

19 ~~(2) The department shall keep a record of the places of practice of persons who hold regular licenses~~

20 ~~or trainee licenses. A notice required to be given by the board or department to a person who holds a regular or~~

21 ~~trainee license may be given by mailing it to the person at the address last given to the department.~~

22 ~~(3) All licensed hearing aid dispensers shall notify the board of any change of address within 30 days~~

23 ~~of the change. A trainee shall notify the board of any change of address within 10 days of the change.~~

24 ~~(4)(2) (a) When licensed hearing aid dispensers and trainees work at the same permanent place of~~

25 ~~business, the licensed hearing aid dispenser Each permanent place of business shall designate one licensed~~

26 ~~hearing aid dispenser who is not a trainee as the person in charge. There must be one licensed dispenser in~~

27 ~~charge at a permanent place of business.~~

28 ~~(b)(3) The licensed hearing aid dispenser in charge of a permanent place of business shall:~~

- 1 (i) ~~is responsible and accountable under the disciplinary authority of the board for the conduct of~~
 2 ~~trainees using that permanent place of business; and~~
- 3 (ii)(a) ~~has maintain~~ custody and control of the business records of that permanent place of business
 4 ~~and is responsible for producing the records during an investigation conducted by the department;~~
 5 (b) produce the business records as requested by the department; and
 6 (c) notify the department in writing of any change of address in the permanent place of business
 7 within 30 days."

8

9 **Section 8.** Section 37-16-303, MCA, is amended to read:

10 **"37-16-303. Bill of sale -- ~~medical evaluation requirements -- waiver.~~** (1) Any person who
 11 ~~practices the selling, fitting, or dispensing of hearing aids and related devices shall~~ A licensed hearing aid
 12 dispenser shall, upon the sale of a prescription hearing aid ~~or related device~~, deliver to the customer a bill of
 13 sale that must contain:

14 (a)(1) the seller's signature and license number, the name and address of the seller's permanent
 15 place of business, and, if different from the permanent place of business, the address ~~of the place of practice at~~
 16 ~~which~~ where the sale was concluded;

17 (b)(2) a description of the make and type of the prescription hearing aid or related device furnished
 18 and the amount charged;

19 (c)(3) any warranty or guaranty ~~and the right to cancel, as well as the terms of the warranty or~~
 20 ~~guaranty and the right to cancel~~ return policy provided or the lack of any warranty or return policy;

21 (d) ~~the condition of the hearing aid or related device and whether it is new, used, or reconditioned;~~

22 (e) ~~a provision that maintenance service for the hearing aid or related device is available; and~~

23 (4) the right to cancel, if applicable, under Title 30, chapter 14, part 5; and

24 (f)(5) the following statement, in boldface, 12-point type: "If you have any questions regarding your
 25 consumer rights with respect to hearing aids ~~and related devices~~, contact the ~~state Board of~~ State of Montana
 26 Hearing Aid Dispensers Program." The statement must also list the current ~~telephone number~~ website address
 27 and mailing address of the board's office department.

28 (2) (a) ~~Except as provided in subsection (2)(b), a hearing aid dispenser may not sell a hearing aid to~~

1 a person unless the person has presented to the hearing aid dispenser a written statement signed by a licensed
 2 physician within the previous 6 months that states that the person's hearing loss has been medically evaluated
 3 and that there are no medical factors or conditions that render hearing aid use inadvisable as a treatment or
 4 remedy for hearing loss.

5 ~~(b) If the prospective hearing aid purchaser is 18 years of age or older, the hearing aid dispenser may~~
 6 ~~give that person the opportunity to waive the requirements of subsection (2)(a) in accordance with the~~
 7 ~~disclosure, waiver form, and instructional brochure requirements of the U.S. food and drug administration~~
 8 ~~regulations found at 21 CFR 801.420 and 21 CFR 801.421."~~

9

10 **Section 9.** Section 37-16-402, MCA, is amended to read:

11 **"37-16-402. ~~Application~~ Hearing aid dispenser license required -- qualifications -- fee.** (1) An
 12 applicant for a license shall pay a fee fixed by the ~~board and commensurate with the costs of processing and~~
 13 ~~administering the application and related functions of the board~~ department and shall show to the satisfaction of
 14 the ~~board~~ department that the applicant:

15 ~~(1) is a person of good moral character;~~

16 ~~(2)(a)~~ has a current license as an audiologist under Title 37, chapter 15; or

17 ~~(b)~~ (i) has an education equivalent to a 4-year course in an accredited a high school diploma or
 18 equivalent; or holds a current license as an audiologist under Title 37, chapter 15;

19 (ii) meets training requirements established by department rule; and

20 ~~(3)(iii)~~ is free of contagious or infectious disease has passed an examination prescribed by
 21 department rule.

22 (2) An applicant who has not met the training and examination requirements in this section may
 23 apply for a trainee hearing aid dispenser license as prescribed in this chapter and department rule."

24

25 **Section 10.** Section 37-16-408, MCA, is amended to read:

26 **"37-16-408. Deposit of fees, fines, and costs.** Fees, fines, and costs collected under this chapter,
 27 except those collected by a justice's court, must be deposited in the state special revenue fund for the use of
 28 the ~~board~~ department, subject to appropriations and 37-1-101(6)."

1

2 **Section 11.** Section 37-16-411, MCA, is amended to read:

3 **"37-16-411. Revocation or suspension of license -- investigations -- fines.** (1) The ~~board~~
4 ~~department~~ may, at its discretion or upon written complaint of an aggrieved person, investigate an alleged
5 violation of this chapter by a licensee or applicant for licensure. If the investigation discloses a probable
6 violation of this chapter or ~~board~~department rules, the ~~board~~department may institute a proceeding pursuant to
7 the provisions of ~~37-1-136 and 37-1-137~~ 37-1-403.

8 (2) A licensee or license applicant may be sanctioned as provided in ~~37-1-312~~ 37-1-406 for ~~any of~~
9 ~~the following causes:~~ unprofessional conduct defined in 37-1-410 or department administrative rules.

10 ~~(a) being convicted of a felony, subject to chapter 1, part 2, of this title. The record of the conviction or~~
11 ~~a certified copy from the clerk of the court for the district where the conviction occurred or certification by the~~
12 ~~judge of the court is conclusive evidence of the conviction, except that if the person has been pardoned by a~~
13 ~~governor or the president of the United States, the conviction does not constitute grounds for imposing~~
14 ~~sanctions.~~

15 ~~(b) securing a license under this chapter through fraud, deceit, or false statements;~~

16 ~~(c) the personal use of a false name or alias in professional practice;~~

17 ~~(d) violating any of the provisions of this chapter;~~

18 ~~(e) obtaining a fee or making any sale by fraud or misrepresentation;~~

19 ~~(f) knowingly employing, directly or indirectly, any suspended or unlicensed person to perform any~~
20 ~~work covered by this chapter;~~

21 ~~(g) using or causing or promoting the use of any advertising matter, promotional literature, testimonial,~~
22 ~~guarantee, warranty, label, brand, insignia, or any other representation, however disseminated or published,~~
23 ~~that is improbable, misleading, deceptive, or untruthful;~~

24 ~~(h) representing that the services or advice of a person licensed to practice medicine or possessing~~
25 ~~certification as an audiologist will be used or made available in the selection, fitting, adjustment, maintenance,~~
26 ~~or repair of hearing aids and related devices if that is not true or using the terms "doctor", "clinic", "hearing~~
27 ~~clinic", "state registered", or other similar words, abbreviations, or symbols that tend to connote the medical~~
28 ~~profession when that use is not accurate;~~

- 1 ~~(i) permitting another to use a license or certificate;~~
- 2 ~~(j) using any method of advertising prohibited by trade practice rules 1 through 17 of the federal trade~~
- 3 ~~commission;~~
- 4 ~~(k) directly or indirectly giving or offering to give or permitting or causing to be given money or~~
- 5 ~~anything of value to any person who advises another in a professional capacity as an inducement to influence~~
- 6 ~~others to purchase or contract to purchase products sold or offered for sale by a hearing aid dispenser or~~
- 7 ~~influencing persons to refrain from dealing in the products of competitors;~~
- 8 ~~(l) unethical conduct or gross incompetence or negligence in the performance of professional duties,~~
- 9 ~~including repeated failure to make indicated medical referrals of customers;~~
- 10 ~~(m) selling a hearing aid or related device to a person who has not been given tests using appropriate~~
- 11 ~~established procedures and instrumentation in fitting hearing aids or related devices, except for the sale of a~~
- 12 ~~replacement hearing aid or a related device of the same make and model within 1 year of the original sale;~~
- 13 ~~(n) falsifying hearing test or evaluation results or any associated client records;~~
- 14 ~~(o) refusing to cooperate with an investigation by the board by:~~
- 15 ~~(i) failing to furnish requested records or documents;~~
- 16 ~~(ii) failing to furnish a complete explanation of matters referred to in the complaint;~~
- 17 ~~(iii) failing to respond to a subpoena issued by the board;~~
- 18 ~~(iv) willfully misrepresenting any relevant fact to a board investigator; or~~
- 19 ~~(v) attempting to discourage a potential witness from cooperating with a board investigator or from~~
- 20 ~~testifying by using threats, harassment, extortion, or bribery."~~

21

22 **NEW SECTION. Section 12. Repealer.** The following sections of the Montana Code Annotated are

- 23 repealed:
- 24 2-15-1740. Board of hearing aid dispensers.
 - 25 37-16-201. Meetings -- organization.
 - 26 37-16-203. Compensation of members -- expenses.
 - 27 37-16-304. Right to cancel -- return of hearing aid or related device -- notice -- refund -- dispensing fee
 - 28 rules.

- 1 37-16-405. Trainee license.
- 2 37-16-406. Admission of licensees from other states.
- 3 37-16-413. Penalty for unlawful practice -- injunction.
- 4 - END -